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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,076	11/09/2001	Bruno Colin	BONN-062	7935
7590	06/29/2004		EXAMINER	
James C Lydon Suite 100 100 Daingerfield Road Alexandria, VA 22314			HANDY, DWAYNE K	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 06/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,076

Applicant(s)

COLIN, BRUNO

Examiner

Dwayne K Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/07/2001</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 13-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by McNeely et al. (6,296,020). McNeely teaches a fluid circuit for microfluidic systems that controls fluid flow through the system by use of passive valves. The passive valves act to impede flow of solutions past the stopping means until enough force builds to allow the solution to overcome the barrier. The embodiments of the device most relevant to the instant claims are shown in Figures 2A-2J and 11A-11D. The operation of the fluid circuit shown in Figures 2A-2J is detailed in columns 6 and 7. As described in column 6 and 7, fluid flows through the two channels in response to the stopping means present in each channel and at their junctions. Fluid flows through channel 2 until point "b" is reached and then fluid flow stops. The fluid then flows through channel 1 until it reaches the outlet of channel 1 and its junction with channel 2. McNeely also
Once the fluid reaches the intersection of the two channels, flow continues from

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both channels along the combined paths. In Figure 11C, McNeely shows a "receptacle" in a channel. It is the position of the Examiner, however, that the channels shown in Figures 2A-2J are sufficient enough to meet the limitations of the instant claims. In several of the Figures (5 and 8 series), McNeely shows multiple receptacles connected in series.

3. Claims 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Naka et al. (EP 0 803 288). Naka et al. disclose a device for analyzing a sample comprised of a channel network and a suction-generating element. The embodiment of the device most relevant to the instant claims is shown in Figures 5A-5D and described in columns 16 and 17. As shown in Figures 5A-5D, the device has a receptacle (3) with an inlet (2A) and outlet (2B), a suction generating chamber (1) and a bypass channel (6). Fluid flows down the channel through the receptacle (analytical area) due to the suction pressure and then stops. If there is an excess of suction pressure, fluid then flows through the bypass channel until the fluid from both channels reach the suction chamber.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeely et al. (6,296,020) in view of Kellogg et al. (6,143,248). McNeely teaches every element of claims 18 and 19 except for a channel having a cross sectional area significantly greater than the branch connection. Kellogg teaches a microfluidic device formed from a network of microchannels on a rotatable disk. Fluid flow in the disk is controlled through the use of centrifugal force to overcome passive valves such as capillary stops. The valve embodiment from Kellogg most relevant to the instant claims is shown in Figures 2A and 2B and described in columns 18-20. The valve is formed by varying the cross sectional area between two channels. Fluid is stopped at the point where the cross section changes until a force is applied. This force drives the fluid through the valve (col. 18, lines 19-35). It would have been obvious to one of ordinary skill in the art to combine the valve teachings from Kellogg with

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the device of McNeely. One would add the change in cross sectional area to provide additional valving mechanism in the device.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeely et al. (6,296,020) in view of Shartle et al. (5,230,866). McNeely teaches every element of claims 21-24 except for one of the receptacles being associated with a buffer supply and a measuring step where the volume of a fluid is determined by a chamber or capillary volume. Shartle teaches a dilution system comprised of microfluidic channels. The device includes a buffer supply in the form of a glycine buffer (columns 28-29). The glycine buffer is used to dilute and resuspend a reagent. One would add the buffer to the device of McNeely in order to dilute samples flowing in the device.

As for the method of claims 22-24, McNeely teaches a method of using a passive flow system which includes flowing a fluid through a microfluidic network until the fluid flow is stopped at a receptacle until displacement of the sample occurs due to sample being present at the intersection of the a channel and receptacle (Example 2, column 7, line 65 – column 8, line 39). McNeely does not teach a volume measuring step. Shartle teaches a capillary flow system which uses passive flow control devices such as capillary stop junctions. The flow system contains measurement capillaries or chambers to measure a sample volume. In use, the flow directing chambers act to divert a portion of the sample into the sample measuring chamber having a predetermined volume (column 15, line 30 – column 16, line 68). The sample is then diluted for examination. This

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diversion of the sample fluid into a chamber of known volume is a calculation of a sample volume since the volume of the chamber is known. It would have been obvious to one of ordinary skill in the art to combine the teaching of the use of a measuring chamber from Shartle with the methods of flow from McNeely. One would add the measuring chamber to provide a known volume of sample for analysis.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mian et al. (6,709,869) and Sheppard, Jr. et al. (6,656,430) show further examples of microfluidic systems on a disc with capillary valve systems for fluid control. Lei et al. (6,637,463) and McNeely et al. (6,591,852 and 6,601,613) display microfluidic circuits controlled with passive valve components. Handique et al. (6,130,098) control the movement of microdroplets in a microchannel with bubble formation. Burdon et al. (6,572,830) teach the use of capillary stops in their multilayered system. Hillman et al. (5,300,779) disclose using a capillary stop in a microfluidic channel.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
June 21, 2004


Jill Warden
Supervisory Patent Examiner
Technology Center 1700